UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,082	07/06/2001	Geert Maertens	2752-50	7439

7590 02/02/2004

NIXON & VANDERHYE P.C.
8th Floor
1100 North Glebe Rd.
Arlington, VA 22201-4714

EXAMINER	
WHISENANT, ETHAN C	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 02/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,082	MAERTENS ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *29,31-33,36-42,46,48,49,52 and 53* is/are allowed.

6)☒ Claim(s) *24-27,34,35,43 and 50* is/are rejected.

7)☒ Claim(s) *28,30,44,45,47,51 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/256,568.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

FINAL REJECTION

1. The applicant's Response (filed 04 NOV 03) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 24-52** is/are pending.

Please note that Claim 33 was not included in the list of pending claims filed with the 04 NOV 03 response. I have considered this to be a typo. I have used the Claim 33 filed as a new claim in the Preliminary Amendment filed 06 JUL 01 as the currently pending Claim 33. See below:

33 (As Currently Pending). The method according to claim 32 wherein said amplification method is PCR, LCR, NASBA, TAS or amplification by means of Qb replicase.

Please clarify.

Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

SEQUENCE Rules

2. This application still fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Raw Sequence Listing Error Report. See also the Notice To Comply With Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

RESPONSE TO APPLICANT'S AMENDMENT AND/OR ARGUMENTS

3. Applicant's arguments regarding the prior art rejections have been fully and carfully considered and are deemed to be persuasive. As a result, **Claim(s) 24-52** are deemed to be allowable over the prior art of record.

NONSTATUTORY DOUBLE PATENTING

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. **Claim(s) 24-26, 37, 39 42** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-2 of US Patent No. 6,495,670. Although the conflicting claims are not identical, they are not patentably distinct from each other.

6. **Claim(s) 24-25, and 27** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 of US Patent No. 6,051,696. Although the conflicting claims are not identical, they are not patentably distinct from each other.

7. **Claim(s) 34 and 50** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-2 of US Patent No. 6,495,670 or over Claim 1 of US Patent No. 6,051,696 as applied above and further in view of the Stratagene Catalog (1988).

Claims 1-2 of US Patent No. 6,495,670 teach all of the limitations of Claim 34 except

this claim does not teach placing the reagents into a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Claims 1-2 of US Patent No. 6,495,670 with the teachings of the Stratagene Catalog wherein the reagents of Claims 1-2 of US Patent No. 6,495,670 are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

Claims 1 of US Patent No. 6,051,696 teach all of the limitations of Claim 50 except this claim does not teach placing the reagents into a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Claims 1-2 of US Patent No. 6,051,696 with the teachings of the Stratagene Catalog wherein the reagents of Claims 1-2 of US Patent No. 6,051,696 are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

8. **Claim(s) 24-27 and 35** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of US 6,051,696. Although the conflicting claims are not identical, they are not patentably distinct from each other.

9. **Claim(s) 43** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 11 of US 5,846,704. Although the conflicting claims are not identical, they are not patentably distinct from each other.

10. **Claim(s) 34** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 of US 6,051,696 as applied above and further in view of the Stratagene Catalog (1988).

Claim 1 of US 6,051,696 teach all of the limitations of Claim 34 except this claim does not teach placing the reagents into a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based

assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Claim 1 of US 6,051,696 with the teachings of the Stratagene Catalog wherein the reagents of Claim 1 of US 6,051,696 are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

RESPONSE TO APPLICANT'S AMENDMENT AND/OR ARGUMENTS

11. Applicant's traversal regarding the obvioussness type double patenting rejection has been fully and carfully considered but is not deemed to be persuasive. In para 11 of paper no. 072303 Claims **Claim(s) 34 and 50** were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-2 of US Patent No. 6,495,670 or over Claim 1 of US Patent No. 6,051,696 in view of the Stratagene Catalog (1988). **Claim(s) 34** was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 of US 6,051,696 and further in view of the Stratagene Catalog (1988).

The applicant argues that it is improper for the examniner to use a secondary reference [i.e. Stratagene (1988)] as a basis for an obviousness-type double patenting rejection. In response, the examiner respectfully points out that for an ODP-Obviousness analysis, "prior art" means one or more claims of a potentially conflicting patent or application, alone or in combination, with some other prior art within the meaning of 35 USC 102.

CLAIM OBJECTIONS

12. **Claim(s) 28, 30, 44-45, 47, 51 and 54** is/are objected to because it is dependent upon a rejected independent base claim.

CONCLUSION

13. Claims pending: **Claims 24-54**.

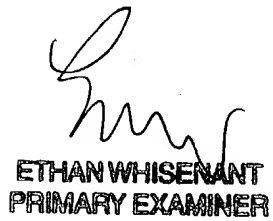
Claim(s) 29, 31-33, 36-42, 46, 48-49 and 52-53 is/are allowable while **Claim(s) 24-28, 30, 34-35, 43-45, 47, 50-51 and 54** is/are rejected and/or objected to for the reason(s) set forth above.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (571) 272-0745.

The fax number for this Examiner is (571) 273-0754. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



ETHAN WHISENANT
PRIMARY EXAMINER

Art Unit 1634